

## Message Text

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64

ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EA-09 ISO-00 OES-05 /037 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

ARA/CAR:JETHYDEN(INFO)

EA/ROC:CWFREEMAN(INFO)

AF/W:EWLOLLIS(INFO)

EA/ROC:CWFREEMAN (INFO)

----- 095443

P 022210Z MAR 76

FM SECSTATE WASHDC

TO AMEMBASSY BRIDGETOWN PRIORITY

AMEMBASSY LAGOS PRIORITY

AMEMBASSY TAIPEI PRIORITY

UNCLAS STATE 050858

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BB, NI, TW

SUBJECT: FDA ADVISORY - FAULTY MANUFACTURING PRACTICES  
AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-216-6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED:

RAVOCAINE HCL. 0.4 PERCENT (BRAND OF PROPROXYCAINE HCL,  
NF), AND NOVOCAIN 2 PERCENT (BRAND OF PROCAIN HCL, USP)  
WITH LEVOPHED 1:30,000 (BRAND OF LEVARTERENOL AS  
BITARTRATE); COOK-WAITE LABS, INC., NEW YORK, NY 10016;  
INJECTABLES 1.8 ML. AND 2.2 ML. CARTRIDGES; 50 CARTRIDGES  
PER CAN.

LOT NUMBERS:

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THESE PRODUCTS HAVE LOT NUMBERS CONSISTING OF THREE

LETTERS FOLLOWED BY TWO DIGITS. ALL LOTS OF CARTRIDGES WITH AN "L" IN THE SECOND POSITION ARE BEING RECALLED. ALSO, ALL LOTS WITH THE FOLLOWING COMBINATIONS IN THE FIRST TWO POSITIONS ARE BEING RECALLED: AN, CN, LN, PN,

RN, UN.

DISTRIBUTION: FROM 1/1/74 AND 8/8/75

MANUFACTURER:

STERLING DRUG, INC.  
33 RIVERSIDE AVENUE  
RENSSELAER, NY 12144

RECALLING FIRM:

A.  
COOK-WAITE LABS., INC.  
90 PARK AVENUE  
NEW YORK, NY 10016

B.  
WINTHROP PRODUCTS  
90 PARK AVENUE  
NEW YORK, NY 10016

REASON FOR ADVISORY (RECALL):

THROUGH VARIOUS INSPECTION REPORTS AND AT CONFERENCES HELD WITH THE CORPORATION'S RESPONSIBLE OFFICIALS, FDA ALLEGED THAT THE PRODUCTS WERE NOT AND HAD NOT BEEN MANUFACTURED IN CONFORMANCE WITH CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS AND THAT THERE WAS A QUESTION OF PRODUCT STERILITY. AFTER SEVERAL MORE MEETINGS AND IN-DEPTH REVIEWS OF BATCH RECORDS OF "STERILE" DRUG PRODUCTS, THE FIRM INSTITUTED A RECALL OF THE INJECTABLE PRODUCTS INVOLVED.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES  
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TO DETERMINE IF THEY HAVE BEEN INFORMED OF THE DETAILS OF THE RECALL AND IF THEY HAVE RECEIVED THE RCA GLOBAL CABLES SENT BY THE FIRM TO ALL FOREIGN DISTRIBUTORS ON AN INDIVIDUAL BASIS CONCERNING THIS RECALL. POSTS MAY ALSO WISH TO CONTACT HOST COUNTRY DRUG CONTROL AUTHORITIES INFORMING THEM OF THE RECALL SO THAT THEY MAY TAKE SUCH ACTIONS AS THEY DEEM APPROPRIATE.

3. FOREIGN CONSIGNEES AS FOLLOWS:

(1) STERLING DRUG, INTERNATIONAL, C/O A. S. BRYDER AND  
SONS (BARBADOS) LTD., BRIDGETOWN, BARBADOS, W.I.  
(2.2 ML)

(2) STERLING PRODUCTS (NIGERIA) LTD. LAGO, NIGERIA  
(FOR GHANA) (2.2 ML)

(3) STERLING PRODUCTS INTERNATIONAL, INC., WINTHROP  
LABS., INC., TAIPEI, TAIWAN, CHINA (2.2 ML) INGERSOLL

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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MANUFACTURES, DRUGS, FOOD & DRUG REGULATIONS, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 02 MAR 1976  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
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**Disposition History:** n/a  
**Disposition Reason:**  
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**Drafter:** JRWEINROTH, M.D.: AMS  
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**Film Number:** D760079-0898  
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**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
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**Line Count:** 128  
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**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
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**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
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**Review Authority:** ShawDG  
**Review Comment:** n/a  
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**Review Date:** 02 JUN 2004  
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Margaret P. Grafeld  
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EO Systematic Review  
04 MAY 2006

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**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - FAULTY MANUFACTURING PRACTICES AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-216-6)  
**TAGS:** OGEN, ETRD, TBIO, BB, NI, TW, FDA  
**To:** BRIDGETOWN  
TAIPEI  
**Type:** TE  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006